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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,792	02/24/2004	Robert G. Turcott	A04P3001-US1	3760

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EXAMINER	
HOLMES, REX R	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,792	TURCOTT, ROBERT G.	
	Examiner	Art Unit	
	Rex Holmes	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/11/07 have been fully considered but they are not persuasive. Applicant argues that Bornzin does not disclose determining the correct pacing intervals for a plurality of different heart rates. In response Bornzin discloses determining correct pacing interval for each of a plurality of different heart rates (Col. 8, ll. 33-38). Columns 4 & 5, summarizes the Bornzin patent as a device that automatically optimizes pacing intervals for each level of the patients activity (different heart rates).

2. Applicant further argues that Carlson does not teach optimizing pacing interval during periods of relative inactivity. Carlson discloses a pacemaker with a hemodynamic pulse pressure sensor that utilizes an accelerometer and threshold values to determine motion so that measurements can be taken during relative steady states of hemodynamic conditions to minimize motion artifacts (Carlson, Col. 3, ll. 4-12 & Col. 7, ll. 17-21; claims 1 and 4). Claim 4 clearly states that the controller includes a means for identifying from the accelerometer signal a time of physical inactivity.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14-18 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin (U.S. Pat. 5,891,176).

5. Regarding claims 14, Bornzin discloses monitoring the patients heart rate (Col. 7, ll. 5-10), determining correct pacing interval for each of a plurality of different heart rates (Col. 8, ll. 33-38; Col. 4), storing the information and hemodynamic response, determining a preferred pacing interval based on the stored information automatically without human interaction (Col. 4, ll. 21-30).

6. Regarding claim 15, the optimal pacing regime differs based on activity and the parameters are continually changed based on the performance volume which is derived from the heart rate (e.g. Col. 8, ll. 45-50).

7. Regarding claims 16, the optimization routine can be done every hour or every day (e.g. Col. 8, ll. 56-60).

8. Regarding claims 17, information is stored for each range (e.g. Col. 9, ll. 57-65).

9. Regarding claims 18, parameters are updated and fine tuned to achieve hemodynamically optimal performance (e.g. Col. 6, ll. 60-67).

10. Regarding claims 21, Bornzin discloses that each time the performance surface occurs it is updated and this does not have to occur continuously (e.g. Col. 4, ll. 21-30).

11. Regarding claims 22, Bornzin discloses that the stored values are relative to measures corresponding to hemodynamic performance (e.g. Col. 4, ll. 21-30).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-5, 8-9, 10-13 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin in view of Carlson (U.S. Pat. 6,366,811).

14. Bornzin discloses a hemodynamically optimal pacing system as described in detail above, and further discloses that it utilizes an accelerometer and hemodynamic data to determine motion (Col. 7, ll. 52-55), but Bornzin does not specifically disclose that when significant motion is present that it either stops pacing and/or storing information that correlates to the pacing. However, Carlson discloses a pacemaker with a hemodynamic pulse pressure sensor that utilizes an accelerometer and threshold values to determine motion so that measurements can be taken during relative steady states of hemodynamic conditions to minimize motion artifacts (Carlson, Col. 3, ll. 4-12 & Col. 7, ll. 17-21; claims 1 and 4). Regarding claims 1-5, 8-9, 10-13 and 23-26, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Bornzin with the motion sensing techniques of Carlson in order to provide the system with the predictable results of a automatic optimization pacing system with a means of minimizing motion artifacts in the signal by sensing and pacing only when the patient is in a state of minimal motion.

15. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin in view of Carlson as applied to claim 1 above, and further in view of Salo et al. (U.S. Pub. 2001/0031993 hereinafter "Salo").

16. Bornzin in view of Carlson discloses that claimed subject matter as disclosed in detail above, but Bornzin in view of Carlson fails to disclose that a plurality of relative measures for each pacing interval are stored. However, Salo discloses that the hemodynamic data is stored in an array and is used to arrive at a particular pacing mode configurations yielding optimum hemodynamic performances (e.g. ¶¶ 60, 90). Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of Bornzin in view of Carlson with the array data storage as taught by Salo in order to produce the predictable result of a automatically optimizing pacemaker with a storage that is fast and organized in order to optimize the pacing parameters as quickly as possible.

17. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin as applied to claim 1 above, and further in view of Salo et al. (U.S. Pub. 2001/0031993 hereinafter "Salo").

18. Bornzin discloses that claimed subject matter as disclosed in detail above, but Bornzin fails to disclose that a plurality of relative measures for each pacing interval are stored. However, Salo discloses that the hemodynamic data is stored in an array and is used to arrive at a particular pacing mode configurations yielding optimum hemodynamic performances (e.g. ¶¶ 60, 90). Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of Bornzin with the array data storage as taught by Salo in order to produce the predictable result of a automatically optimizing pacemaker with a storage that is fast and organized in order to optimize the pacing parameters as quickly as possible.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rex Holmes
Examiner
Art Unit 3762

George Evanisko
Primary Examiner
Art Unit 3762

9/10/07